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NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER	
HA, JULIE	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/797,393	OLSEN ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-98* is/are pending in the application.

4a) Of the above claim(s) *90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-89 and 91-96* is/are rejected.

7)☒ Claim(s) *39-55 and 57-89* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed November 28, 2006 is acknowledged. Cancellation of claims 1-37 are acknowledged. Claims 38-96 are pending in this application.

Restriction

1. Applicant's election without traverse of Group I (Claims 38-89 and 91-96), drawn to a method for producing alcohol, in the reply filed on November 28, 2006 is acknowledged. Claim 90 is withdrawn from consideration being drawn to a nonelected Invention. Claims 38-89 and 91-96 are examined under the merits in the application.

Objection-Minor Informalities

2. The abstract of the disclosure is objected to because the 3rd line of the abstract contains a legal word "said". The abstract must be free of legal phraseology. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: There is a "fifth aspect" missing in between paragraphs [0014] and [0015].

Appropriate correction is required.

Objection-Claims

4. Claims 39-55 and 57-89 are objected to because of the following informalities: Claims are dependent on cancelled Claim 1. Appropriate correction is required.

Rejection-35 U.S.C. § 112, 2nd

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 38, 47-48 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 (b) recites "a temperature 0 to 20°C below the initial gelatinization temperature". It is unclear what "gelatinization temperature" is. Claims 47 and 48 recites ratio of between 0.30 and 5.00 AFAU/AGU and Claim 59 recites ratio between acid alpha-amylase activity and glucoamylase activity between 0.35 and 5.00 AFAU/AGU, but it is unclear what the units of the ratio are.

Rejection-35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 91-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Veit et al (PG Pub 2004/0091983).

9. The instant claims are drawn to a mashing process comprising treating a mash with an acid alpha-amylase , wherein the acid alpha-amylase is derived from *Aspergillus niger* and has the amino acid sequence shown in SEQ ID NO:1.

10. Veit et al discloses a method of producing ethanol from a starch containing material, comprising steps of (a)-(e) where step (c) discloses liquefaction in the presence of an alpha-amylase having an amino acid sequence SEQ ID NO:1 (see Claim 39). The reference also discloses that milled and liquefied whole grain are also known as mash (see paragraph [0045]). The reference further discloses the thermostable acid alpha-amylases as used herein are the alpha-amylase selected from the group *Aspergillus oryzae* and niger derived from *Aspergillus* (see paragraph [0116]).

Rejection-35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 38, 40-45, 47-48, 55-59, 62-64, 65-70 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen NW (US Patent # 4316956) in view of Yoshizumi et al (US Patent # 4092434).

15. The instant claims are drawn to a process for production of an alcohol product comprising the sequential steps of (a) providing a slurry comprising water and granular starch, (b) holding said slurry in the presence of an acid alpha amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of said granular starch for a period of 5 minutes to 12 hours, (c) holding said slurry in the presence of an acid alpha amylase and a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce ethanol and, (d) optionally recovering the ethanol; the acid alpha amylase is from *B. lichenformis* and pH during step (b) is in the range or 3.0-7.0, 3.5-6.0, 4.0-5.0 for both steps (b) and (c). The instant claims are also drawn to the acid alpha-amylase and the glucoamylase added in steps (b) and (c) are in a ratio of between 0.30 and 5.00 AFAU/AGU; acid alpha-amylase activity is present in an amount of 50-500 AFAU/kg of DS; glucoamylase activity is present in an amount of 20-200 AGU/kg of DS; and the ratio between acid alpha-amylase activity and glucoamylase activity is between 0.35 and 5.00 AFAU/AGU.

16. Lutzen NW (US Patent # 4316956) teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The abstract further teaches a slurry containing granular corn starch in water, is adjusted to a Ca^{2+} content and pH to pH 5. The reference teaches that pH optimum for the ethanol producing microorganism is pH 3-7, 25° to 38°C (see column 5, lines 37-40). Alpha amylase (*B. licheniformis*) and glucoamylase are added, and the suspension stirred on a water bath for 18 hours at 60°C. This reads on the temperature limitation of step (b) in claim 89. After 18 hours, the slurry are transferred to a fermentation flask cooled to 30°C and to the flask are added: yeast extract solution, antibiotics, yeast suspension, and glucoamylase, and the fermentation is conducted at 30°C for 6 days (see columns 11 and 12, Example 1). The reference teaches the dosage range for alpha-amylase is 0.02 to 2.0 FAU/g of starch, preferably 0.05-0.6 FAU/g (see column 6, lines 54-57) and the glucoamylase dosage of 0.05 to 10.0 AGU/g of starch, preferably, 0.2 to 2.0 AGU/g starch (see column 5, lines 59-61). Additionally, Example 1 teaches using 65 μl alpha-amylase to 135 μl of glucoamylase (see column 11, Example 1). This reads on claims 47-48 and 57-59. The reference further teaches that the fermentation of a granular starch slurry having 25-40% starch by weight (see column 8, lines 15-17). This reads on claims 62-64. The reference is silent regarding the pH range of step (c). However, it is obvious to assume that since the pH was adjusted to pH 5 (see column 11, line 66) and 98% sulfuric acid was present in the fermentation trap (see column 12, lines 14-16), it would have been obvious to optimize using sulfuric acid to get the optimal pH of the reaction absent ay critical

limitation (see paragraph 18 below). The difference between the reference and the instant claim is that the reference does not teach the step (a) from 5 minutes to 12 hours.

17. However, Yoshizumi et al (US Patent # 4092434) teach that method for manufacturing alcohol or alcohol beverage which, by avoiding the high-temperature, high-pressure cooking step of the prior art, saves energy to be used and the amount of cooling water, and which eliminates a danger in operation that stems from the operation using a high temperature and high pressure, and which lowers construction and maintenance costs of the equipment by the alteration from high pressure equipment to atmospheric pressure equipment (see column 1, lines 61-68 and column 2, lines 1-3).

18. Therefore, it would have been obvious to the ordinary skilled in the art to optimize the processing conditions of Yoshizumi et al on the teachings of Lutzen NW. There is a reasonable expectation of success since Yoshizumi et al teach that by avoiding the high-temperature, high-pressure step would save energy, and eliminates a danger in operating at high temperature and pressure. By optimizing the reaction condition by increasing the temperature, the reaction time would be decreased. There is a reasonable expectation of success since MPEP states the following: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA*

1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); *In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). There is reasonable expectation of success since "*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"

19. Claims 38-39, 46, 49-51, 54, 61-64, 71-73, 74, 75-80 and 81-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen NW (US Patent # 4316956) in view of Lantero et al (US Patent # 5231017).

20. The instant claims are drawn to a process for production of an alcohol product (fuel) comprising the sequential steps of (a) providing a slurry comprising water and granular starch, (b) holding said slurry (5-60% DS granular) in the presence of an acid alpha amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of said granular starch for a period of 5 minutes to 12 hours, (c) holding said slurry in the presence of an acid alpha amylase and a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce ethanol and an enzyme activity xylanase or cellulose for a period of 5 to 190 hours, and, (d) optionally recovering the ethanol and the acid alpha amylase is an acid fungal alpha amylase obtained from *Aspergillus niger* or *Aspergillus oryzae* and glucoamulase is obtained from *Aspergillus niger*. The claim is also drawn to the alcohol product is a beer.

21. As described in paragraph 16, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). Furthermore, the reference teaches that the addition of the alpha amylase from *Aspergillus oryzae* saccharifies dextrins to maltotriose and maltose. The reference teaches that although the purpose of the alpha amylase is to liquefy the starch, its saccharification propensity also make the alpha amylase some part of the saccharifying enzyme content (see column 6, lines 7-14). The reference further teaches that the traditional process for making beer wherein grains are hydrolyzed by malt results in a wort with a significant nonfermentable polysaccharide content, and, in turn, a beer with a significant polysaccharide content (see column 1, lines 32-36). The reference also teaches the solids content of a wet mill starch slurry is

close to 40% starch by weight (see column 11, lines 9-11). This reads on claim 74. The difference between the reference and the instant claims is that the reference does not teach acid fungal alpha amylase from *Aspergillus niger* and glucoamylase obtained from *Aspergillus niger*.

22. However, Lantero et al (US Patent #5231017) teach a process for producing ethanol from raw materials containing a high dry solids mash level, and that contain fermentable sugars or constituents which can be converted into sugars, comprising steps (a) liquefaction, (b) saccharification, (c) fermentation, and (d) recovering the ethanol (see column 1, lines 49-65). The reference also teaches that it may also be advantageous to add some enzymes to the liquefied mash during saccharification and/or during fermentation. Examples of such enzymes are cellulases, hemicellulases, phosphatase, exo- and endoglucanases, and xylanase (see column 3, lines 65-68 to column 4, lines 1-2). This reads on claim 61. Furthermore, the reference teaches that in commercial fuel alcohol production, the liquefied whole corn mash is diluted with thin stillage prior to fermentation (see column 6, Example 4). Additionally, the reference teaches the acid fungal protease is derived from *Aspergillus niger* (see column 2, lines 15-27). The reference further teaches that the steps of saccharification and the fermentation steps are carried out either simultaneously or separately, preferably the saccharification and fermentation steps are carried out simultaneously. When carried out simultaneously, the glucoamylase derived from *Aspergillus niger* and the acid fungal protease derived from *Aspergillus niger* can be introduced as a single mixture composition, sold by Solvay Enzymes, Inc. (see column 3, lines 44-54). This reads on

claims 49-51 and 54. Additionally, results obtained from the simultaneous saccharification and fermentation of whole corn mash with the addition of acid fungal protease (AFP) increased the rate and level of ethanol obtained. The reaction without AFP present, more glucose remained unfermented (see column 5, lines 28-36). This reads on claims 71-72. The reference further teaches that liquefied corn mash containing glucoamylase and inoculated with yeast, fermentation are conducted for 60 hours (see column 8, Example 10). This reads on claims 81-86. Furthermore, the reference teaches whole ground corn was liquefied, fermentation flasks were prepared as in Example 1, except the mash DS was adjusted to 27.76% DS (w/w) (see column 10, lines 1-4). This reads on claims 62-64. The reference further discloses the process wherein the raw materials are whole ground corns, cobs, corns, grains, milo or cereals (see Claim 4). This reads on claim 73.

23. Therefore, it would have been obvious to the ordinary skilled in the art to combine the use of acid fungal alpha amylase from *Aspergillus* (*niger* or *oryzae*) since the two strains are from the same genus and both glucoamylase and acid fungal amylase can be obtained from the *Aspergillus* strains (see Lantero Patent, column 3, lines 50-54). There is a reasonable expectation of success since carrying out the saccharification and the fermentation steps using the glucoamylase and acid fungal alpha amylase together increased the rate and the level of ethanol obtained. Although the Lantero reference is silent in regards to holding time under step b) from 10 minutes to 6 hours and step c) for a period of 70 to 140 hours and 80 to 130 hours, it would be obvious to optimize to acquire through routine experimentation to obtain the optimal

levels absent and critical (see paragraph 18). The skilled artisans motivation is to optimize the production of the product, with less time and less effort.

24. Claims 38 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen (US Patent # 4316956) in view of Katkocin et al (US Patent #4536477).

25. The instant claims are drawn to a process for production of an alcohol product comprising the sequential steps of (a) providing a slurry comprising water and granular starch, (b) holding said slurry in the presence of an acid alpha amylase and a glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of said granular starch for a period of 5 minutes to 12 hours, (c) holding said slurry in the presence of an acid alpha amylase and a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce ethanol and, (d) optionally recovering the ethanol and the glucoamylase is obtained from a strain of *Aspergillus*, *Talaromyces* or *Clostridium*.

26. As described above in paragraph 16, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The difference between the reference and the instant claims are that the reference does not teach that the glucoamylase is obtained from a strain of *Aspergillus* (*Aspergillus niger*), *Talaromyces* or *Clostridium*.

27. However, Katkocin et al (US Patent #4536477) teach glucoamylase useful for the hydrolysis of starch (see column 1, lines 6-9). The reference teaches the glucoamylase produced by two new strains of *Clostridium* that were isolated from mud hot springs

(see column 2, lines 12-16). The reference further teaches that the thermostability of the purified glucoamylase was compared with that of two other known gulcoamylases. Results indicates that the glucoamylase from *Clostridium* show superior stability at 70°C and pH 5 or 6 over the glucoamylases produced by *Talaromyces duponti* and *Aspergillus niger* (see column 6, lines 52-68).

28. Therefore, it would have been obvious to the ordinary skilled in the art to combine the teachings of Katkocin et al with Lutzen to produce ethanol. There if a reasonable expectation of success since it would be desirable to hydrolyze starch by conducting the liquefaction and saccharification steps simultaneously in the same reaction mixture. This could be accomplished if a glucoamylase were available that would saccharify the liquefied starch at pH values between 6 and 7 where alpha amylase is active. Additionally, the glucoamylase would have to be sufficiently thermostable at this pH to permit the saccharification reaction to be carried out at a temperature where the reaction rate is fast enough to be useful (see Katkocin Patent, column 1, lines 36-45).

29. Claims 38, 51-52 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen (US Patent # 4316956) in view of Veit et al (PG Pub 2004/0091983).

The instant claims are drawn to a process for production of an alcohol product comprising the sequential steps of (a) providing a slurry comprising water and granular starch, (b) holding said slurry in the presence of an acid alpha amylase and a

glucoamylase at a temperature of 0°C to 20°C below the initial gelatinization temperature of said granular starch for a period of 5 minutes to 12 hours, (c) holding said slurry in the presence of an acid alpha amylase and a glucoamylase and a yeast at a temperature between 10°C to 35°C to produce ethanol and, (d) optionally recovering the ethanol; and the acid alpha-amylase is an alpha-amylase having an amino acid sequence of SEQ ID NO:1. The claim is also drawn to granular starch is obtained from dry milling.

30. As described in paragraph 16, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The reference does not teach an acid alpha-amylase having an amino acid sequence of SEQ ID NO:1.

31. However, Veit et al (PG Pub 2004/0091983) teach a method of producing ethanol from a starch containing material, comprising steps of (a)-(e) where step (c) discloses liquefaction in the presence of an alpha-amylase having an amino acid sequence SEQ ID NO:1 (see Claim 39). The reference also discloses that milled and liquefied whole grain are also known as mash (see paragraph [0045]). The reference further discloses the thermostable acid alpha-amylases as used herein are the alpha-amylase selected from the group *Aspergillus oryzae* and niger derived from *Aspergillus* (see paragraph [0116]). Additionally, the reference discloses that a fermentation process where the starting material is whole grain which have been partitioned into finer parts, preferably by dry milling (see paragraphs [0012], [0026], [0030], [0035] and [0036])

32. Therefore, it would have been obvious to the ordinary skilled in the art to combine the teachings of Lutzen and Veit et al to produce alcohol product. There is a reasonable expectation of success since Veit et al discloses that milled and liquefied whole grain are also known as mash and teaches similar steps of producing ethanol (see Claim 38).

33. Claims 91 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walmsley et al (US Patent # 3712820).

34. The instant claims are drawn to a mashing process comprising (a) forming a mash comprising between 5% and 100% barley malt (w/w of the grist); (b) prior to, during or after a) adding an acid alpha-amylase and at lease one enzyme selected from the list comprising: a protease, cellulose and a maltose generating enzyme; (c) attaining within 15 minutes of a) an initial incubation temperature of at least 70°C; (d) following c) incubating the mash at a temperature of at least 70°C for a period of time sufficient to achieve an extract recovery of at least 80%.

35. Walmsley et al teach aqueous slurry of a raw starch-containing material, preferably a cereal grain such as barley, is heated to 40-55°C at which temperature is subjected to the action of a discrete proteolytic enzyme and, optionally, a discrete alpha-amylase enzyme, then heated to 65 to 90°C at which temperature it is subjected to the action of a discrete alpha-amylase enzyme (see abstract). The reference teaches in the production of a nitrogenous wort for use in the manufacture of nondistilled fermented beverages such as beers, ales, lagers, and the like, and to the fermented

beverages derived therefrom (see column 1, lines 38-42). Furthermore, the reference teaches that in the brewing of beer, the wort is commonly produced by mashing a slurry of barley malt and adjuncts (see column 1, lines 50-54). Additionally, the reference teaches that the cereal adjunct is introduced in an amount of between about 10 and 60% more preferably between about 42 and about 55% by weight based on the weight of the adjunct cereal grains relative to the weight of cereal grain substrate in the aqueous slurry (see column 3, lines 18-21). Furthermore, the reference teaches the wort may be evaporated to a syrup which may then be stored until required, say, to increase the throughput of a conventional process at peak times. In this event, the syrup, before use, is diluted to provide a wort. Advantageously, the syrup contains between about 70 and about 85% by weight total solids, preferably about 70 to 80% (see column 12, lines 11-17). This reads on claims 91 and 96.

36. Although, the reference is silent as to incubating the mash at a temperature of at least 70°C for a period of time sufficient to achieve an extract recovery, it would have been obvious to the ordinary skilled in the art to optimize the temperature to achieve the recovery level. The MPEP states the following: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration

between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); *In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). There is a reasonable expectation of success since "*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"

37. Claims 38 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen NW (US Patent # 4316956) in view of James et al (US Patent # 3880742).

38. The instant claims are drawn to a process for production of an alcohol product comprising the steps of (a)-(d), wherein step (b) is performed in the presence of an enzyme activity selected from the group consisting of xylanase, cellulase and phytase.

39. As described above in paragraph 16, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The difference between the reference and the instant claims is that the reference does not teach an enzyme activity of cellulase in step (b).

40. However, James et al (US Patent # 3880742) teach the b-glucan added to the mash should preferably be active in the high temperature stage of alpha-amylase activity following starch liquefaction if optimum β-glucan degradation is to be effected. The β-glucanase enzyme preparations obtained will normally exhibit further forms of enzymatic activity, including cellulose and alpha-amylase activity (see column 6, lines 53-57 and lines 63-66).

41. Therefore, it would have been obvious to the ordinary skilled in the art to combine the use of enzyme cellulase in step (b), since the "*normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages*". There is a reasonable expectation of success since James et al teaches that the use of the enzyme preparation in such enzymatic brewing processes has the additional advantage of reducing the quantities of such enzymes to be added separately to the mash.

42. Claims 38 and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lutzen NW (US Patent # 4316956) in view of Leach et al (US Patent # 3922196) and in view of Gray et al (Journal of Bacteriology, 1986, 166(2): 635-643).

43. The instant claims are drawn to a process for production of an alcohol product comprising the steps of (a)-(d), wherein the acid alpha-amylase is an acid bacterial alpha-amylase and is derived from a strain of *B. licheniformis*, *B. amyloliquefaciens*, or *B. stearothermophilus* alpha-amylase.

44. As described above in paragraph 16, Lutzen teaches a process of fermentative production of ethanol in the presence of non-gelled or granular starch particles, alpha amylase and a glucoamylase (see abstract). The difference between the reference and the instant claims is that the reference does not teach the acid alpha-amylase is an acid bacterial alpha-amylase and is derived from a strain of *B. licheniformis*, *B. amyloliquefaciens*, or *B. stearothermophilus* alpha-amylase.

45. However, Leach et al (US Patent # 3922196) teach a process for converting granular starch to a soluble hydrolysate comprising agitating a mixture of granular starch, water, and an alpha-amylase and at least one saccharification enzyme at a temperature between the normal initial gelatinization temperature or the starch and the actual gelatinization temperature of the starch (see abstract). The reference further teaches that the granular starch is solubilized with a bacterial alpha-amylase enzyme preparation if a first step which may alternatively include a saccharifying enzyme such as glucoamylase or beta-amylase, and this first step is thereby followed by a saccharification or conversion step (see column 8, lines 12-18). The reference further

teaches that the preferred sources of alpha-amylases include certain species of *Bacillus* microorganism, viz., *B. subtilis*, *B. licheniformis*, *B. coagulans* and *B. amyloliquefaciens* (see column 3, lines 32-35). The difference between the reference and the instant claim is that the reference does not teach *B. stearothermophilus*.

46. However, Gray et al (Journal of Bacteriology, 1986, 166(2): 635-643) teach that the amylases of *B. licheniformis* and *B. stearothermophilus* are related as indicated by homology at the DNA and protein levels. They belong to an enzyme family with members which also include the amylases of *B. coagulans* and *B. amyloliquefaciens* (see p. 642, Discussion).

47. Therefore, it would have been obvious to the ordinary skilled in the art to use the alpha-amylase from these species *B. licheniformis*, *B. amyloliquefaciens*, or *B. stearothermophilus.* There is a reasonable expectation of success since Gray et al teach that the amylases of *B. licheniformis* and *B. stearothermophilus* are related (see paragraph 46) and transformation of E. coli with vectors containing either gene resulted in the synthesis and secretion of active enzymes similar to those produced by the parental organisms (see abstract). Additionally, Leach et al teach that the enzymes from *B. licheniformis* are unusually effective in the liquefaction of granular starch. Since the enzymes are related, it would have been obvious to use alpha-amylase from *B. licheniformis*, *B. amyloliquefaciens*, or *B. stearothermophilus*.

Conclusion

48. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Julie Ha
Patent Examiner
AU1654

ANISH GUPTA
PRIMARY EXAMINER